UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

JANET ADAMS and RANDY ADAMS	§	
	§	
v.	§	CIVIL NO. 4:19-CV-870-SDJ
	§	
MEDTRONIC, INC., ET AL.	§	

MEMORANDUM ADOPTING IN PART AND MODIFYING IN PART THE REPORT AND RECOMMENDATION OF THE UNITED STATES MAGISTRATE JUDGE

Came on for consideration the Report and Recommendation of the United States Magistrate Judge in this action (the "Report"), this matter having been referred to the magistrate judge per 28 U.S.C. § 636. On August 25, 2020, the magistrate judge entered proposed findings of fact and recommendations contained in the Report, (Dkt. #23), recommending that: (1) the Court deny the Motion to Dismiss Plaintiffs' First Amended Complaint Pursuant to Rule 12(b)(6) and Brief in Support Filed by Defendant Covidien Holding Inc., (Dkt. #12); and (2) that Plaintiffs be required to replead their claims.

Having received the Report, and no timely objections being filed, the Court determines that the findings and conclusions contained in the Report should be **ADOPTED in part** and **MODIFIED in part**.

I. BACKGROUND

Plaintiff Janet Adams underwent a colorectal surgery at Baylor Medical Center. The operating surgeon, Dr. Laurie Novosad, performed part of that surgery using an EEA surgical stapler manufactured by Defendant Covidien Holding Inc.

("Covidien").[1] Janet Adams, along with her husband Randy Adams, allege that, during surgery, the EEA stapler "misfired and cut Plaintiff Janet Adams's intestines, without the staples engaging." On removal from state court, the Adamses bring six claims: (1) negligence and strict liability for defective design; (2) negligence and strict liability for manufacturing defect; (3) strict liability for failure to warn; (4) breach of implied warranty; (5) breach of express warranty; and (6) loss of consortium. (Dkt. #9, the "Amended Complaint").

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows a party to move for dismissal of a complaint when the plaintiff has failed to state a claim upon which relief can be granted. Under Rule 8(a)(2), a complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). A claim is plausible when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct

[1] For purposes of this memorandum, the Court will refer to Defendants Covidien Holding Inc., Covidien LP, Covidien Sales LLC, and Medtronic, Inc. collectively as "Covidien." The Court also notes that, in its Motion, Covidien states that the Adamses have misnamed the manufacturer of the EEA stapler as being Medtronic, Inc. rather than Covidien Holding Inc.

alleged." *Id.* Although a probability that the defendant is liable is not required, the plausibility standard demands "more than a sheer possibility." *Id.*

In assessing a motion to dismiss under Rule 12(b)(6), the "court accepts all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff." *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir. 2007). Legal conclusions "must be supported by factual allegations." *Iqbal*, 556 U.S. at 679. These allegations must go beyond mere labels, conclusions, and formulaic recitations of the elements of a claim. *Twombly*, 550 U.S. at 555. To determine whether a plaintiff has pleaded enough to "nudge[its] claims . . . across the line from conceivable to plausible," a court draws on its own "judicial experience and common sense." *Iqbal*, 556 U.S. at 679–80 (quoting *Twombly*, 550 U.S. at 570) (internal quotation marks omitted). This threshold is met if the court determines the plaintiff pleaded "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly*, 550 U.S. at 556).

When considering a Rule 12(b)(6) motion, review is limited to the complaint, any documents attached to the complaint, and any documents attached to the motion to dismiss that are central to the claim and referenced by the complaint. *Lone Star Fund V (U.S.), L.P. v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir. 2010).

III. DISCUSSION

Covidien argues that the Court should dismiss with prejudice all six of the Adamses' claims because the Amended Complaint does not state plausible claims, but rather conclusions "masquerading as facts." Covidien further contends that the Adamses fail to cite "specific support" for each claim.

In response, the Adamses first concede that the Amended Complaint does not plead sufficient facts to support its implied breach of warranty and express breach of warranty claims (Counts IV and V). Then, as stated in the Report, the Adamses ask that the Court grant them leave to amend their claims to cure the pleading deficiencies in Counts IV and V "and any others that Defendants have identified." (Dkt. #23). The magistrate judge found that the pleading deficiencies in the Adamses' Amended Complaint were not clearly incurable and thus that the Adamses deserved the opportunity to replead their claims.

The Court agrees, although it takes this opportunity to clarify which counts the Adamses must replead and why those counts are deficient as currently pleaded.

A. Negligence or Strict Liability for Defective Design

Pleading a Texas negligence claim requires that a plaintiff plead: (1) the existence of a duty; (2) a breach of that duty; and (3) damages proximately caused by the breach. *W. Inv., Inc. v. Urena*, 162 S.W.3d 547, 550 (Tex. 2005) (citation omitted). "It is customary and proper for a plaintiff to plead strict liability and negligence as alternative theories;" however, a negligence-products-liability claim is a distinct claim from a strict-products-liability claim. *Castillo v. Bos. Sci. Corp.*, No. 7:20-CV-123, 2020 WL 5608510, at *3 (S.D. Tex. Sept. 18, 2020) (citations omitted). "The care taken by the supplier of a product in its preparation, manufacture, or sale[] is not a consideration in strict liability; this is, however, the ultimate question in a negligence action." *Id.* (quoting *Gonzales v. Caterpillar Tractor Co.*, 571 S.W.2d 867, 871 (Tex. 1978)).

Pleading a strict-liability design-defect claim in Texas requires a plaintiff to plead: "(1) the product was defectively designed so as to render it unreasonably dangerous; (2) the defect was the producing cause of the injury for which the plaintiff seeks recovery; and (3) a safer alternative design existed." *Castillo*, 2020 WL 5608510, at *3 (citations omitted). "Under Texas law, a safer alternative design is one that would have prevented or significantly reduced the risk of the claimant's personal injury . . . without substantially impairing the product's utility." *Id.* (citation and internal quotation marks omitted). The safer alternative design "must also be economically and scientifically feasible," and cannot be a "substantially different product." *Id.* (citation omitted).

Regarding the Adamses' negligence claim, Covidien argues that "Plaintiffs do not identify any conduct by Covidien that breached the standard of care, or identify how Covidien's alleged breach proximately caused Ms. Adams's injuries." In support, Covidien cites to *Steen v. Medtronic, Inc.*, in which a district court concluded that a plaintiff failed to state a negligence claim where the plaintiff "allege[d] multiple alternative legal conclusions relating to [the d]efendant's due care, manufacture, and design[, but] allege[d] no facts in support of such deficiencies." No. 3:10-CV-936-L, 2010 WL 2573455, at *3 (N.D. Tex. June 25, 2010). The court also noted that the plaintiff's chief allegation was that the medical device at issue had been "mal-positioned." The court concluded that, without more specificity, this allegation went to placement of the medical device by the doctor, not a defect in its design. *Id.*

Covidien's reliance on *Steen* is misplaced. Unlike in *Steen*, the Adamses allege that "Defendant's surgical staplers contained . . . a design or manufacturing defect that would result in a stapler failing to fire staples, despite proper utilization by a surgeon." The Adamses also allege that, according to the surgeon, the EEA stapler "cut but did not fire staples." The Adamses further allege that "[a] reasonably prudent manufacturer of [surgical staples] would also know that a stapler failing to fire staples could cause serious injury." It is this alleged defect in the EEA stapler's design—the stapler's penchant for cutting without firing—of which the Adamses are "critical." *See* (Dkt. #12 at 5) ("But what aspects of the stapler's design or manufacture are Plaintiffs critical of and why? How did Covidien's actions in designing and manufacturing the stapler fall below any applicable duty? Plaintiffs do not say."). Thus, the Adamses have alleged what conduct by Covidien breached the standard of care and how that breach proximately caused Ms. Adams's injuries.

However, the Adamses have not adequately pleaded the existence of a safer alternative design, which is a required element of both negligence- and strict-liability-based design-defect claims. *Flynn v. Am. Honda Motor Co., Inc.*, No. 4:11-CV-3908, 2015 WL 75270, at *5 (S.D. Tex. Jan. 6, 2015) (citing TEX. CIV. PRAC. & REM. CODE § 82.005) (holding that plaintiffs "must establish the elements of a design defect claim set out in Texas statute, including the economic feasibility of a safer alternative design, in order to prevail under a breach of warranty or a negligence theory").

The Adamses allege that "there were safer alternative designs of EEA staplers available to Defendants at the time the EEA stapler at issue in this case was sold.

Those designs were reasonable[] and economically and technologically feasible at the time the stapler at issue in this case was sold." (Dkt. #9 ¶ 45). This is a mere conclusion unsupported by facts. The Adamses do not allege what alternative stapler designs existed,[2] how those staplers compared economically, or how those staplers were safer. Without such specifics, the Court cannot draw a reasonable inference that Covidien is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 678.

The Adamses' burden is not a high one. In *Ardoin v. Stryker Corp.*, the court found the plaintiff's allegations that a hip-replacement product's components could have been designed without dimensional discrepancies and metallurgical weaknesses were sufficient for Rule 8(a). No. 4:18-CV-2192, 2019 WL 4933600, at *3 (S.D. Tex. Oct. 7, 2019). An examination of the record in *Ardoin* shows that the plaintiff had alleged that safer hip replacement designs would include acetabular shells that did not contain dimensional discrepancies and bone screws that were not prone to breaking, cracking, fracturing, and loosening.[3] The court admitted these alternative-design allegations were not "detailed," but nevertheless distinguished them from allegations in which plaintiffs provided no alternative designs, did not allege the

[2] The only specific alternative the Adamses discuss—surgical sutures—are an alternative product altogether, not an alternative design to surgical staples. *See Fearrington v. Bos. Sci. Corp.*, 410 F.Supp.3d 794, 804 (S.D. Tex. 2019) (holding that the plaintiffs' allegations that there existed alternative surgeries that used devices made from different materials do not suffice as allegations that alternative designs existed for the products at issue).

[3] Plaintiff's Second Amended Complaint and Demand for Jury Trial ¶ 30, *Ardoin v. Howmedica Osteonics Corp.*, No. 4:18-CV-02192, 2019 WL 6656011 (S.D. Tex. Oct. 7, 2019).

designs would reduce risk of death, or did not allege the alternatives were economically or technologically feasible. *Ardoin*, 2019 WL 4933600, at *3.

Thus, to sufficiently plead negligence and strict-liability theories for design defect, the Adamses need only identify economically and technologically feasible alternative EEA stapler designs that do not cut the patient without firing the staples. Because the Adamses have not so pleaded, the design-defect claim is DISMISSED without prejudice.

B. Negligence and Strict Liability for Manufacturing Defect

A strict-liability manufacturing-defect claim requires that a plaintiff alleges: (1) the product at issue deviated from its specifications or planned output; (2) the deviations rendered the product unreasonably dangerous; (3) the defect existed at the time the product left the seller; and (4) the defect was a producing cause of the plaintiff's injuries. *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.3d 797, 800 (Tex. 2006).

The Adamses have not sufficiently alleged that the EEA stapler deviated from its specifications or planned output. They allege only that certain EEA staplers manufactured by Covidien were manufactured "without a component that resulted in a failure to 'fire' the staples." Even taking this allegation as true, as the Court must, the Adamses have not plausibly alleged a manufacturing defect because they have not specified which component was missing from the stapler or how that component's absence caused the EEA stapler to misfire. Alleging that some component was missing, without specifying which component, is no more specific than merely

alleging there was a "manufacturing flaw" because the EEA stapler "malfunctioned and did not perform as intended or designed." *See Elmazouni v. Mylan, Inc.*, 220 F.Supp.3d 736, 741 (N.D. Tex. 2016) (holding that a plaintiff must plead specifics about the manufacturing defect, not merely that the product malfunctioned).

A complaint that does not specify the manufacturing defect nor the causal connection between the failure of the specific manufacturing process and the specific defect is "impermissibly conclusory and vague." *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011). In *Funk*, the plaintiff alleged that a prosthetic hip "contained a manufacturing defect in that it was manufactured in such a manner that impurities, residues and bacteria remained on the prosthesis in violation of the FDA standards and requirements and in violation of the manufacturing processes and design approved by the FDA." *Id.* The plaintiff further alleged that the prosthesis "deviated, in its construction or quality, from the specifications or planned output." *Id.* The Fifth Circuit affirmed the trial court's dismissal of the plaintiff's manufacturing-defect claim, holding that the complaint was impermissibly conclusory and vague because the plaintiffs did not specify the manufacturing defect, how the manufacturing process failed, or the causal connection between the two. *Id.*

The same is true here. The Adamses do not specify which component was missing from the EEA stapler, nor do they allege any other specific manufacturing defect. They likewise do not specify how Covidien's manufacturing process failed or how that failure caused the defect. Thus, the facts alleged are too generic to allow the Court to draw a reasonable inference that a manufacturing defect existed. *Iqbal*,

556 U.S. at 678. Therefore, the Court concludes that the Adamses' manufacturing-defect claim is insufficiently pleaded, and that claim is DISMISSED without prejudice.

C. Strict Liability for Failure to Warn

To sufficiently plead a failure-to-warn claim in Texas, a plaintiff must allege:

> (1) a risk of harm that is inherent in the product or may arise from the intended or reasonably anticipated use of the product; (2) the product supplier actually knew or should have reasonably foreseen the risk of harm at the time the product was marketed; (3) the product contains a marketing defect; (4) the absence of a warning renders the product unreasonably dangerous to the ultimate user or consumer of the product; and (5) the failure to warn constitutes a causative nexus in the product user's injury.

Wright v. Ford Motor Co., 508 F.3d 263, 275 (5th Cir. 2007) (citing *Sims v. Washex Mach. Corp.*, 932 S.W.2d 559, 562 (Tex. App.—Houston [1st Dist.] 1995, no writ)).

Further, as Covidien points out, the "learned intermediary doctrine" applies in Texas for cases involving medical devices. *See Porterfield v. Ethicon*, 183 F.3d 464, 468 (5th Cir. 1999) (citations omitted) ("The learned intermediary doctrine applies in medical products liability actions in Texas."). "Under this doctrine, a product manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers." *Id.* at 467–68 (citing *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591–92 (Tex. 1986)). Thus, a plaintiff must allege, in addition to the elements above, that a manufacturer failed to properly warn the plaintiff's physician and that this failure was a "producing cause" of the plaintiff's injuries. *See Gonzalez v. Bayer Healthcare*

Pharm., Inc., 930 F.Supp.2d 808, 818 (S.D. Tex. 2013) ("Because Plaintiff does not allege that the warning to her healthcare provider was inadequate nor identify the warnings or materials which her doctor received or reviewed, much less demonstrate that the doctor would not have prescribed [the product] if the warning had been different, and does not allege facts necessary to show causation, she fails to [meet her pleading burden]") (citing *Pustejovsky v. Pliva*, 623 F.3d 271, 276 (5th Cir. 2010)).

The Adamses' Amended Complaint alleges the first four elements above: (1) the EEA stapler had an inherent risk of harm, or one that could arise from a reasonably anticipated use of the product—*i.e.*, that it would cut patients but not fire staples; (2) Covidien not only should have reasonably foreseen, but actually knew the risk of harm at the time the EEA stapler was marketed; (3) the EEA stapler contained a marketing defect—that Covidien intentionally concealed from the FDA, the public, and physicians the true number of EEA stapler malfunctions and injuries caused by the EEA stapler; and (4) not publishing the true numbers of injuries and malfunctions rendered the EEA stapler unreasonably dangerous because physicians would use the EEA stapler without knowing the true risks involved. (Dkt. #9 ¶¶ 23–38, 54–59).

However, the Adamses have not sufficiently pleaded the final element in light of the learned-intermediary doctrine. That is to say, the Adamses have not adequately alleged that Covidien's failure to warn physicians and the public of the EEA stapler's true risks caused Ms. Adams's surgeon to use the EEA stapler where she otherwise would not have. In product-liability cases, plaintiffs must plead a "causative nexus"

between the failure to warn and the injuries incurred. In cases where the learned-intermediary doctrine applies, plaintiffs must allege that the manufacturer's failure to warn the intermediary caused the intermediary to act differently than she otherwise would have. This means the Adamses are required to plead that Ms. Adams's surgeon would not have used the EEA stapler had she known the true risks that a proper warning from Covidien would have disclosed. Thus, this claim is DISMISSED without prejudice.

D. Breach of Implied Warranty

To state a breach-of-implied-warranty claim in Texas, plaintiffs must allege: (1) the defendant sold goods;[4] (2) the goods were defective at the time of sale; (3) the plaintiff was injured as a result; and (4) the plaintiff provided pre-suit notice to the defendants about the alleged breach. *Howard v. Forest River, Inc.*, No. 9:15-CV-162, 2017 WL 9325286, at *11 (E.D. Tex. Nov. 14, 2017) (citation omitted). The Court finds that the Adamses have adequately pleaded the first three elements. However, as the Adamses concede, their Amended Complaint does not adequately allege the fourth element—pre-suit notice—but they ask for a chance to replead it. *See* (Dkt. #13 at 9). Thus, this claim is DISMISSED without prejudice.[5]

[4] Covidien argues that, because the EEA stapler was not sold to the Adamses, they cannot sue for breach of implied warranty. But Texas law states that "no privity of contract is required in a suit for personal injuries" and that "a person who has not purchased a product can still sue for breach of an implied warranty." *Ackermann v. Wyeth Pharm.*, 471 F.Supp.2d 739, 744 (E.D. Tex. 2006).

[5] Covidien argues that the Adamses' pre-suit settlement discussions did not discuss a breach-of-implied-warranty claim as required by Texas law. *See Melody Home Mfg. Co. v. Morrison*, 502 S.W.2d 196, 203 (Tex. Civ. App.—Houston [1st Dist.] 1973, writ ref'd n.r.e.). The Court will give the Adamses the opportunity to replead this claim, and, if they cannot

E. Breach of Express Warranty

Under Texas law, a breach-of-express-warranty claim requires a plaintiff to allege: (1) an affirmation or promise made by the buyer to the seller; (2) that such affirmation or promise was part of the basis for the bargain; (3) that the goods failed to comply with the affirmation or promise; (4) that there was a financial injury; and (5) that the failure to comply was the proximate cause of the financial injury to the buyer. *Scott v. Dorel Juvenile Grp. Inc.*, 456 F. App'x 450, 456 (5th Cir. 2012).

As Covidien points out, the Adamses have not pleaded any specific affirmation or promise made to them or to Ms. Adams's healthcare provider. Nor have they alleged that any such affirmation or promise was the basis for the bargain or that the goods failed to comply with that promise. *See Ackermann v. Wyeth Pharm.*, 471 F.Supp.2d 739, 744 (E.D. Tex. 2006) (holding that, on summary judgment, the plaintiff needed to both show evidence that an express warranty existed and that the plaintiff relied on it). Thus, this claim is DISMISSED without prejudice.

F. Loss of Consortium

Because Mr. Adams's loss-of-consortium claim is derivative of Ms. Adams's claims, this claim must also be DISMISSED without prejudice, although the Court identifies no additional pleading defect concerning this claim.

IV. CONCLUSION

It is, therefore, **ORDERED** that the Report and Recommendation of the United States Magistrate Judge, (Dkt. #23), should be and is hereby **ADOPTED in**

allege that they gave Covidien specific notice of their intent to file a breach-of-implied-warranty claim, Covidien can re-urge its argument at that time.

part and **MODIFIED in part**. The Court adopts the following findings and conclusions:

- The Court adopts the magistrate judge's finding that the Adamses' breach-of-implied-warranty and breach-of-express-warranty claims are inadequately pleaded. (Dkt. #23 at 3).
- The Court adopts the magistrate judge's conclusion that the Adamses should be given the opportunity to replead their claims because: (1) the Adamses "have only amended their complaint a single time, as a matter of course following removal," (Dkt. #23 at 4), and (2) "it is not clear the defects in Plaintiffs' Amended Complaint are incurable," (Dkt. #23 at 3–4). The Fifth Circuit has held that "[d]istrict courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal." *Great Plains Tr. Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002).
- The Court adopts the recommendation that the Adamses be required to file a Second Amended Complaint on or before fourteen days from the date of this order. (Dkt. #23 at 4).

The Court modifies the following findings and conclusions:

- The Court finds that the Adamses have failed to adequately plead all of their claims, not just their breach-of-implied-warranty and breach-of-express-warranty claims.
- Because the Adamses' claims are inadequately pleaded, Covidien's motion should be granted as to dismissal, but denied as to Covidien's request that the Adamses' claims be dismissed with prejudice.

It is, therefore, **ORDERED** that the Motion to Dismiss Plaintiffs' First Amended Complaint Pursuant to Rule 12(b)(6) and Brief in Support Filed by Defendant Covidien Holding Inc., (Dkt. #12), is **GRANTED in part** and **DENIED in part**, and that each of the Adamses' claims, Counts I–VI of Plaintiffs' First Amended Complaint, (Dkt. #9), are hereby **DISMISSED without prejudice**. It is further **ORDERED** that the Adamses have **fourteen days** from the date of this order to amend their complaint.

So ORDERED and SIGNED this 1st day of October, 2020.

SEAN D. JORDAN
UNITED STATES DISTRICT JUDGE